HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

September 29, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUIRED

Mr. Garry B. Shank
19413 Longmeadow Road
Hagerstown, Maryland 21742

Dear Mr. Shank:

An investigation of your dairy cow operation located in Hagerstown, Maryland, conducted by our investigator on August 29 & 31, 2000, confirmed that you offered three cows for sale for slaughter as human food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

During the inspection, our investigator observed that you sold the following animals for slaughter as human food to [redacted]

1. cow with ear tag number [redacted] sold on 2/11/00
2. cow with back tag # [redacted] sold on 5/1/00
3. cow with back tag # [redacted] sold on 5/10/00

U.S. Department of Agriculture (USDA) analysis of tissue samples collected from the three cows identified above revealed residues of Penicillin in the kidney and liver tissues of all three cows, which exceeded the established tolerance of 0.05 parts per million cited in Title 21, CFR, Part 556.510. The presence of this drug in edible tissue from the animals causes the food to be adulterated.

Our investigation found that you hold animals under conditions which are so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling and for assuring that animals medicated by you have been withheld from slaughter for the appropriate time period to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

The objectionable conditions observed and listed on the FDA-483 issued to you at the conclusion of the investigation include the following:

- Failure to maintain medication/treatment records showing the identity of the animal, the medication dates, the name of the drug, the dosage administered, and the withdrawal time prior to slaughtering.

- Failure to follow the label directions for medications used to treat dairy cows. For example, you administered 20 cc's of Agri-Cillin (Penicillin G Procaine) once a day for two days rather than the recommended dosage of 10 cc's listed on the labeling, and administered the drug directly into the udder rather than intramuscularly, as recommended in the labeling.

- Failure to have a system in place for the review of treatment records prior to offering animals for slaughter as human food to assure that the appropriate withdrawal period was observed. For example, there were no records for the three cows you sold for slaughter which resulted in residues of penicillin in the liver and kidney tissues above the established tolerance for the drug (ear tag [redacted] back tag [redacted]; back tag [redacted]).

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for sale for slaughter as food for human consumption, you are responsible for assuring that your overall operations and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation showing that corrections have been made.

Your reply should be directed to Ms. Rosalie Bucey, Compliance Officer, U.S. Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, telephone number (410) 962-3591, extension 143.

Sincerely,

Lee Bowers
District Director